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Australian/New Zealand Standard

Ultrasonics—Continuous-wave Doppler systems—Test procedures

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Ultrasonics—Continuous-wave Doppler systems—Test procedures

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/17 on Ultrasonic Medical Equipment and issued as a Joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand.

This Standard is identical with and has been reproduced from IEC 1206:1993, *Ultrasonics—Continuous-wave Doppler systems—Test procedures*.

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- (b) **Decimal marker** Substitute a full point for a comma where it appears as a decimal marker.
- (c) **References** The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

*Reference to International Standard
or other publication*

Australian/New Zealand Standard

IEC	AS/NZS
1102	Measurement and characterisation of — ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Ultrasonics—Continuous-wave Doppler systems—Test procedures**

SECTION 1: GENERAL

1.1 Scope

This technical report describes:

- test methods for measuring the performance of continuous-wave ultrasonic Doppler flowmeters, velocimeters, or foetal heart detectors;
- special Doppler test objects for determining various performance properties of Doppler ultrasound systems.

This technical report applies to:

- tests made on an overall Doppler ultrasound system; a system which is not disassembled or disconnected;
- tests made on continuous-wave Doppler ultrasound systems. The same tests can be applied to Doppler ultrasound systems which measure position as well as velocity, such as pulsed and frequency-modulated Doppler systems, although additional tests may then be required.

Electrical safety and acoustic output are not covered in this technical report

1.2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this technical report. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this technical report are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 1102: 1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*

1.3 Definitions

For the purposes of this technical report, the following definitions apply:

1.3.1 direction sensing; directional: Descriptor of a type of Doppler ultrasound system which indicates whether scatterers are approaching or receding from the ultrasonic transducer.

1.3.2 direction resolving; direction separating: Descriptor of a type of **Doppler ultrasound system** in which the **Doppler output** appears at different output terminals, **output channels** or **output devices** depending upon the direction of scatterer motion relative to the transducer.

1.3.3 Doppler frequency; Doppler-shift frequency: Change in frequency of an ultrasound scattered wave caused by relative motion between the scatterer and the transducer. It is the difference frequency between the transmitted and the received wave.

1.3.4 Doppler output; direct output; Doppler frequency output: Voltage at the Doppler frequency or at Doppler frequencies which activates the output device.

1.3.5 Doppler output connector: Electrical connector or that part of a **Doppler ultrasound system** at which the **Doppler output** is available for connection to external output devices.

NOTE – Not all **Doppler ultrasound systems** have a physical connector at which the **Doppler output** is available.

1.3.6 Doppler spectrum: Set of **Doppler frequencies** produced by a **Doppler ultrasound system**.

1.3.7 Doppler test object: Artificial structures used in testing **Doppler ultrasound systems**. They produce ultrasonic reflections that are similar to those produced by the structures on which the **Doppler ultrasound systems** are to be used.

NOTE – **Doppler test objects** are often referred to as phantoms.

1.3.8 Doppler ultrasound system; system: Equipment designed to transmit and receive ultrasound and to generate a **Doppler output** from the difference in frequency between the transmitted and received waves.

1.3.9 non-directional: Descriptor of a type of **Doppler ultrasound system** which is not **direction sensing**.

1.3.10 observed velocity: Component of the velocity of a scatterer that is directed towards or away from the transducers.

1.3.11 operating frequency: The ultrasonic or electrical frequency of operation of an ultrasonic transducer forming part of a **Doppler ultrasound system**.

1.3.12 output channel: Part of a **Doppler ultrasound system** which functionally represents a particular aspect of the **Doppler output**.

NOTE - A **Doppler ultrasound system** may have two **output channels**, each representing a flow in a particular direction.

1.3.13 output device: Any device included in a **Doppler ultrasound system** or capable of being connected to it that makes the **Doppler output** accessible to the human senses.

1.4 Symbols

c is the average speed of sound in a medium.

v is the average speed of the fluid in a flow **Doppler test object**.

Φ is the angle between the sound beam and the axis of the tube, string, band or disc in flow, string, band or disc **Doppler test objects** respectively.

λ is the ultrasonic wavelength.

SECTION 2: OVERALL TESTS OF COMPLETE SYSTEMS

2.1 General considerations

2.1.1 *Types of Doppler ultrasound systems*

A major factor that affects performance testing of a **Doppler ultrasound system (system)** is whether it can be described as **directional**, **non-directional**, or as **direction resolving**. **Directional** or **direction sensing** refers to a type of **system** which indicates whether scatterers are approaching or receding from the ultrasonic transducer. **Non-directional systems** do not indicate direction of scatterer motion. **Direction resolving**, or **direction separating systems** provide for **Doppler output** to appear at different **output channels** depending upon the direction of scatterer motion. Annex A gives descriptions and examples of these different types of **systems**.

2.1.2 *Worst case conditions*

A test method may be applied to determine a particular performance parameter of a **system**. Often a number of quantities can have a bearing on overall performance, each one of which requires the application of a distinct test method. Some of these quantities need to be maximised and others need to be minimised in order to obtain the best overall performance. Considering overall performance, table 1 gives the worst case conditions for key quantities appropriate to **peripheral vascular systems** and the corresponding clause number which describes a suitable test method. Table 1 may need modification to be appropriate for other uses. As an example, if the noise as measured in 2.2.4 is maximised this will lead to worst case overall performance; conversely, minimising noise will lead to maximised performance. The situation for spatial response (see clause 2.4), is discussed in the rationale (see annex B).

Table 1 – Worst case quantities, and corresponding subclause numbers

Worst case is the minimum value of:		Worst case is the maximum value of:	
Quantities	Subclause	Quantities	Subclause
Working distance	2.2.3	Noise level	2.2.4
High-frequency response	2.3.1	Low-frequency response	2.3.1
Fixed target effect on sensitivity	2.3.3.2	Distortion	2.3.3.1
Channel separation	2.6.1	Simulator flow error	2.6.2

2.2 Initial conditions

These clauses describe conditions common to all of the tests given in clauses 2.3 to 2.7, as well as a procedure for locating the appropriate **Doppler-shift frequency** and distance ranges to be used for these measurements.

Where a particular type of **system** may be comprised of various combinations of components, it is intended that each combination should be regarded as a separate **system** for testing purposes. For example, a **system** may have various transducer options. In this case, each transducer and output recording or presentation device connected to the basic electronics will define a different **system**. For tests to be meaningful, all instrument controls, particularly the volume or gain controls, should be recorded during the test.

2.2.1 Power supply

To ensure that the stated specifications hold over the range of power supply voltage, tests should be undertaken for the different power line voltages and the worst case test result values reported. The power line voltages are to be used at their nominal values and at 10 % above and below the nominal voltage. For power line operated **systems** the worst case values are those obtained after a specified warm-up time.

Portable battery-operated **systems** weighing less than one kilogram should be tested with no warm-up and only over the time span sufficient to perform each test to simulate typical use. Heavier battery-powered **systems** should be tested under the same conditions as the power line operated **systems**.

For all battery-operated **systems** the results should be the worst case found over the span of battery voltages from the fully charged condition to a nominal end-of-life voltage. Any **system** tuning or adjustment should be done as specified in the instruction supplied to the user. It should be stated whether the nominal life-span of the battery occurs under

continuous or intermittent conditions of use. This allows the manufacturer to select the intended normal battery life for either intermittent or continuous use.

2.2.2 *Test frequency, general conditions*

An initial nominal test **Doppler frequency** as specified by the manufacturer, or 1.0 kHz if none is specified, should be obtained by operating the **system** and transducer with one of the **Doppler test objects** specified in clause 3.1. The sound beam is directed at the appropriate moving portion of the **Doppler test object**, whose speed of operation should be adjusted to produce the nominal test **Doppler frequency** in the **Doppler frequency output** of the **system**. The transducer should be affixed in a clamp capable of translating the transducer along, and at right angles to, the axis of maximum sensitivity of the **system** under test. Alternatively, the **Doppler test object** can be moved to cause the same relative displacements. In both cases, the mounting should allow the angle of the sound beam emitted by the transducer to be changed relative to the moving portion of the **Doppler test object**, while allowing the separation of the transducer and the **Doppler test object** to be changed. The separation adjustment should be independent of the angular adjustments so that the true axial response along the sound beam can be measured.

Where appropriate, and unless otherwise stated, the **Doppler-shift frequency** and the **Doppler output** should be observed and measured on each of the outputs provided for the **system** being tested, with each of the transducers with which it is expected to work. It is recommended that the readings be taken at the **Doppler output connector** if one is available. The single-channel output **systems** usually can be tested by observing their output indication relative to any calibration scales or marks on the **system**.

In the tests that use **Doppler test objects**, as illustrated above, the use of a tissue-equivalent absorber is recommended and described in this technical report. This is done to be sure that the signal levels in the **system** are close to those that will be encountered in practice. It is possible to make these tests in a water bath without absorber and to make corrections for the effects of absorption. In this case, to obtain valid results the gain controls should be set at positions that prevent malfunction, or "overloading" of the **system** from the large echo signals. Overloading in the input circuits can still occur, however, depending on the design. Since this procedure may introduce errors in the case of large aperture, or array transducers, it is not recommended.

2.2.3 *Working distance*

The small vessel **Doppler test object** or string **Doppler test object** (see 3.1.1) is convenient for this test. The tissue-equivalent absorber may be removed only for working distances less than 1 cm. The lateral position of the transducer assembly is adjusted with respect to the moving portion of the small vessel **Doppler test object** while observing the signal level of the **Doppler output** on the selected **Doppler output connector**. The position which maximises the magnitude of the **Doppler output** is located. This process is repeated over a range of separations between the transducer and the moving portion of the **Doppler test object**. The effective spacing between the face of the transducer assembly (measured on the centre line axis of the assembly) and the intersection of the centre line axis of the transducer assembly and the moving portion of the **Doppler test object** is the working distance.

If the **system** includes an automatic gain control circuit, the **Doppler output** may be relatively constant over a large range of distances. The working distance should be taken as the approximate centre of this flat region.

2.2.4 *Zero-signal noise level*

For future reference, the level of the noise components which are found at the **Doppler output connector** when the moving portion (string) of the **Doppler test object** is stopped should be measured using a true-r.m.s. responding power meter, or visually on each **output device**. The observer should be sure that stray reflections within the **Doppler test object** do not influence this test (see 3.1.7). The passband of the power meter should extend over the full frequency range measured for the response of the particular **Doppler output** being tested (see 2.3.1).

2.3 Doppler frequency response

Frequency response tests may be made by using a **Doppler test object** appropriate for the intended clinical use of the **system** positioned at the standard working distance.

Response and accuracy are preferably tested with the small vessel or string **Doppler test object** since these produce a single **Doppler frequency** which is readily measured, even visually on spectrum analyzers. **System** control settings or ranges intended for arterial occlusive diagnosis should be used for tests with this **Doppler test object**. **System** configurations designed for venous diagnosis may be tested using the large vessel or band **Doppler test object**. The disk **Doppler test object** should be reserved for the distortion test specified in 2.3.3.1.

2.3.1 *Frequency response range*

The speed of the moving member (or fluid) in the **Doppler test object** is changed to produce a range of **Doppler frequencies**. The time-average **Doppler output** is measured as a function of **Doppler frequency** or speed of movement, using an r.m.s. or average responding voltmeter and a frequency counter, or other speed-indicating device. If the **Doppler output** has one maximum value, the low-frequency response frequency and the high-frequency response frequency are found from those frequencies at which the output voltage is 0,707 times its maximum value, although other limits may be used if so declared. This same procedure should apply in the case of multiple-peaked response curves where the minimum values between the maxima are not less than 0,707 times the voltage at the greatest maximum.

If the response curve is multiple-peaked (as it generally will be when using loudspeaker output tests) then the smallest value found between the peaks should be taken as defining the minimum detectable signal level. A horizontal line on the graph at this signal level will then intersect the frequency response curve at this minimum and two other points. These two other points are the low- and high-frequency response values and should be quoted as the result of the test, qualified by a statement of the level of this minimum relative to the highest value.